K053236

510(K) SUMMARY

DATE OF SUMMARY:
NOVEMBER 3, 2005

JUL 18 2006

SUBMITTER & CORRESPONDENT IN THE UNITED STATES:
NATIONAL BUSINESS GROUP INC.
2941 61ST. AVE NE
TACOMA
WA 98422
CONTACT# 253-238-6409

MANUFACTURED BY:
RUNBIO BIO TECH CO., LTD
RONGSHENG TECHNOLOGICAL ZONE,
UNIVERSITY ROAD
SHANTOU,
GUANGDONG,
CHINA 515063

DEVICE NAME:
DAVID PREGNANCY TEST (STRIP AND MIDSTREAM)

DEVICECLASSIFICATION NAME:
PREGNANCY, TEST, KIT, HCG, MIDSTREAM, TEST STRIP, OVER-THE-COUNTER

CLASSIFICATION NUMBER:
862.1155

FDA PRODUCT CODE:
LCX

MEDCAL SPECIALTY:
CLINICAL CHEMISTRY

INTENDEND USE:
DAVID PREGNANCY TEST IS A SELF-TESTING IMMUNOASSAY DESIGNED FOR THE QUALITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN THE URINE TO AID IN EARLY DETECTION OF PREGNANCY. IT IS FOR THE OVER-THE-COUNTER-USE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 6 2006

Runbio Biotech Co., Ltd.
c/o Ms. Jessica Vagata
National Business Group Inc.
2941 61st Ave. NE
Tacoma, WA 98422

Re: k053236
Trade/Device Name: David Pregnancy Test (Strip and Midstream)
Regulation Number: 21 CFR§ 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: LCX
Dated: June 19, 2006
Received: June 22, 2006

Dear Ms. Vagata:

This letter corrects our substantially equivalent letter of July 18, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: **K053236**

Device Name: DAVID PREGNANCY TEST (STRIP AND MIDSTREAM)

Indications For Use:

DAVID PREGNANCY TEST IS A SELF-TESTING IMMUNOASSAY DESIGNED FOR THE QUALITATIVE DETERMINATION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN THE URINE TO AID IN EARLY DETECTION OF PREGNANCY. IT IS FOR THE OVER-THE-COUNTER-USE

Prescription Use _____ AND/OR Over-The-Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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